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| 10/091,333 | 03/06/2002 | Paz Einat | EINAT1.1D | 1554 |

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| EXAMINER |
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ASHEN, JON BENJAMIN

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| ART UNIT | PAPER NUMBER |
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1635

DATE MAILED: 03/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/091,333

Applicant(s)

EINAT ET AL.

Examiner

Jon B. Ashen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-39 is/are pending in the application.
- 4a) Of the above claim(s) 12-16 and 24-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/28/2005 has been entered.

Status of Application/Amendment/Claims

2. Applicant's response filed 12/15/2005 has been fully considered. Rejections and/or objections not reiterated from the previous office action mailed 06/15/2005 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 12-39 are pending in this application. Claims 12-16 and 24-39 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 17-23 are currently under examination in this application.

Specification-Objections

3. The amendment filed 12/15/2005 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The amendment of paragraph 0056 to recite, "Isolation of inhibitory antisense RNA is disclosed in Holzmayer (1992)" and paragraph 0059 to recite, "In the latter publication the antisense oligonucleotide is antisense RNA" introduces new matter because Holzmayer et al. and Whitesell et al. (referred to above as "the latter publication") are disclosed in the instant specification as general references but the disclosures of antisense RNA therein are not specifically pointed to or specifically contemplated in the context of the invention as it is now claimed.

Applicant is required to cancel the new matter in the reply to this Office Action.

Priority

4. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. [1] as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent

application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Provisional Application No. 60/056,453, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. No disclosure of RNA molecules that target mRNA encoding a polypeptide having an amino acid sequence of SEQ ID NO: 10 could be located in the abovementioned provisional application. Therefore, the effective filing date of claims 17-19, 21-23 is considered to be 8/21/1998 (Application 09/138,112). The effective filing date of claims 20 and 22 is considered to be the filing date of the instant application, 3/06/2002.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 20 and 22 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons of record set forth in the Action mailed 12/28/2004 and reiterated herein. This is a new matter rejection.

Claims 20 and 22, were newly presented in this Application in the amendment filed 03/17/04. Claim 20 is drawn to an RNA molecule that targets mRNA encoding a polypeptide having the amino acid sequence of SEQ ID NO: 10 that is an antisense

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RNA molecule. Claim 22 is drawn to an RNA molecule that targets DNA encoding a polypeptide having the amino acid sequence of SEQ ID NO: 10. Applicant has pointed to pages 23-27 as support for the limitations set forth in new claims 20 and 22.

However, although support for new claims to RNA molecules that are ribozymes was located, no support could be found for new claims to an RNA molecule that is an antisense RNA or for an RNA molecule that targets DNA.

Response to Arguments-Claim

Rejections 35 U.S.C. § 112

7. Applicant's arguments filed 12/15/2005 have been fully considered but they are not persuasive. Applicant has argued that the present specification incorporates by reference full disclosures of the references listed that "deal" with antisense RNA, including Holzmayer et al. and Whitesell et al., both non-patent literature citations, and that therefore one of ordinary skill in the art would have understood the instant claims drawn to antisense oligonucleotides to encompass antisense RNA (pgs 9-10, remarks).

However, MPEP § C.F.R. 1.57(c) states

"Essential material" may be incorporated by reference, but only by way of an incorporation by reference to a U.S. patent or U.S. patent application publication, which patent or patent application publication does not itself incorporate such essential material by reference. "Essential material" is material that is necessary to:

(1) Provide a written description of the claimed invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and set forth the best mode contemplated by the inventor of carrying out the invention as required by the first paragraph of 35 U.S.C. 112;

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- (2) Describe the claimed invention in terms that particularly point out and distinctly claim the invention as required by the second paragraph of 35 U.S.C. 112; or
- (3) Describe the structure, material, or acts that correspond to a claimed means or step for performing a specified function as required by the sixth paragraph of 35 U.S.C. 112.

The specification states, in regards to antisense oligonucleotides of the invention, that, "AS [antisense] oligonucleotide sequences may be short sequences of DNA, typically 15-30 mer, but may be as small as 7 mer (Wagner et al, 1996), designed to complement a target mRNA of interest and form an RNA:AS duplex" (page 23, lines 21-24) and "An additional mode the interaction of action results from AS with genomic DNA to form a triple helix that may be transcriptionally inactive" (pg. 24, lines 7-10). As set forth in the Action mailed 6/15/06, the language of the instant specification thereby provides support for antisense (AS) that is DNA, not RNA, wherein that DNA forms a RNA:AS duplex (an RNA:DNA duplex) wherein that AS DNA can interact to form a triple helix. Therefore, the required description of antisense oligonucleotides that are RNA antisense oligonucleotides is considered to be essential matter and cannot, as above, be incorporated by reference from Applicant's cited references. Additionally,

See MPEP § 608.01(p) which states:

While the prior art setting may be mentioned in general terms, the essential novelty, the essence of the invention, must be described in such details, including proportions and techniques, where necessary, as to enable those persons skilled in the art to make and utilize the invention.

Specific operative embodiments or examples of the invention must be set forth. Examples and description should be of sufficient scope as to justify the scope of the claims.

In the instant case, Applicant's arguments are not persuasive because the incorporation of essential subject matter by reference to non-patent literature is improper and because the disclosure of the specification lacks specific guidance with regards to the essential novelty or essence of the invention.

8. Claims 17-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The instant claims drawn to RNA molecules that target an mRNA encoding a polypeptide having the amino acid sequence of SEQ ID NO: 10, which reads on a large genus of RNA molecules that "target" the mRNA above, which can have a large number of nucleotide sequences due to codon degeneracy, wherein the RNA molecules are required to function (in light of the disclosures of the specification and dependent claims) to inhibit the expression of the targeted mRNA (i.e., the targeting prevents processing, splicing, transport or translation of the mRNA, results in mRNA degradation or results in a transcriptionally inactive product). However, the specification as filed does not provide an adequate written description of the broad genus of RNA molecules that will function, commensurate with the breadth of what is claimed.

No definition of targets or targeting could be located in the specification as filed. The specification discloses that RNA molecules that are ribozymes that can be

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designed to target a particular mRNA sequence, but no disclosure of ribozyme sequences or ribozymes that were made or used that were targeted to an mRNA encoding a polypeptide of SEQ ID NO: 10 could be located. The specification provides a general discussion of antisense oligonucleotides, which are distinguished from ribozymes, and how those are made and used in the art and indicates that an antisense oligonucleotide as small as 7 nucleotides (a 7-mer) can be used (pg. 23). The specification discloses no functional RNA molecules that target an mRNA encoding a polypeptide of SEQ ID NO: 10 wherein the RNA molecules can be ribozymes or antisense oligonucleotides as above.

The narrow disclosure of the specification which includes no disclosure of any species of the invention, therefore, does not provide an adequate written description of the claimed RNA molecules. The disclosure of the specification is merely prophetic with regard to RNA molecules that will function, as claimed and does not provide a representative number of species of RNA molecules that will function, commensurate with what is being claimed, to inhibit the expression of an mRNA encoding a polypeptide of SEQ ID NO: 10 wherein the primary nucleotide sequence of the mRNA can be highly variant due to codon degeneracy. The specification provides no disclosure of the structure of any RNA molecule that corresponds with the function of targeting any mRNA that encodes the polypeptide of SEQ ID NO: 10 and no distinguishing identifying characteristics of the claimed RNA molecules that would indicate that applicant was in possession of the genus as claimed. Therefore, Applicant has not provided an

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adequate written description of the claimed RNA molecules that would indicate that they were in possession of the claimed invention.

The state of the art at the time the invention was made and even several years post-filing (in view of Applicant's claims to the benefit of an earlier filed application) could not provide the required written description of the claimed invention because the state of the art recognized the unpredictability of inhibiting the expression of a nucleic acid (see Agrawal et al. 2000 - Molecular Medicine Today, Vol. 61, pp. 72-81). Agrawal et al. indicate, in particular regard to antisense methods of gene inhibition in cells of cells *in vitro*, that, "*In vitro*, cellular uptake of antisense oligonucleotides depends on many factors including cell type, kinetics of uptake, tissue culture conditions and chemical nature, length and sequence of the oligonucleotide. Any one of these factors can influence the biological activity of an antisense oligonucleotide. It is therefore appropriate to study each antisense oligonucleotide in its own context and relevant cell line without generalizing the results for every oligonucleotide" (pg. 80, col. 1, 1st paragraph). It is noted here that the same issues that have been outlined above in regards to antisense oligonucleotides are reasonably considered to apply to ribozymes.

MPEP § 2163[R-2] I. states:

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., > Moba, B.V. v. Diamond Automation, Inc., 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003); < Vas-Cath, Inc. v. Mahurkar, 935 F.2d at 1563, 19 USPQ2d at 1116.

The fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. See, e.g., Vas-Cath, Inc., 935 F.2d at 1563-64, 19 USPQ2d at 1117.

Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such

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as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. See, e.g., *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406; *Amgen, Inc. v. Chugai Pharmaceutical*, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991) (one must define a compound by "whatever characteristics sufficiently distinguish it").

An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. > *Enzo Biochem*, 323 F.3d at 964, 63 USPQ2d at 1613.<

In the instant case, Applicant has not provided adequate written description of their invention because the specification does not convey, with reasonable clarity to those of skill in the art, as of the filing date sought, that applicant was in possession of the invention now claimed. Applicant has not shown how the invention was "ready for patenting" such as by the disclosure of the structure of an RNA molecule that targeted an mRNA encoding the polypeptide of SEQ ID NO: 10 (including all nucleotide sequences that differed due to codon degeneracy) that would function, commensurate with the breadth of what is claimed, to inhibit the expression of that mRNA or by describing distinguishing identifying characteristics of the genus of claimed RNAs that would be sufficient to show that the applicant was in possession of a representative number of species from within the broad genus claimed.

Claim Rejections - 35 USC § 102 or 35 USC § 103-withdrawn

9. The rejections of claims 17-20 and 22-23 under 35 U.S.C. 102(e) or 35 USC 103(a) as being anticipated by or obvious over Chang (U.S. Patent 5,912,326) and over Sutcliffe et al. (WO 98/05352) are withdrawn.

Claim Rejections - 35 USC § 102 or 35 USC § 103-maintained and new

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 17-23 remain rejected under 35 U.S.C. 102(e) or 35 USC 103(a) as being anticipated by or obvious over Pavco et al. (U.S. Patent 6,818,447) for the reasons set forth in the Action mailed 12/28/2004 (see response to arguments below).

12. Claims 20 and 22 are rejected under 35 U.S.C. 102(e) or 35 USC 103(a) as being anticipated by or obvious over Monia et al. (U.S. Patent 6,300,132). Monia et al. disclose SEQ ID NO: 10, an antisense oligonucleotide that is 20 nucleotides in length and 80% complementary to an mRNA encoding a polypeptide of SEQ ID NO: 10 (instant nucleotide sequence: SEQ ID NO: 2), that can be an RNA oligonucleotide (columns 5, line 50 bridge to col.6, line 67; Table 1).

Furthermore, since the prior art oligonucleotide meets all the structural limitations of the claims, the prior art oligonucleotide comprises an RNA molecule that is targeted to an mRNA encoding a polypeptide having the amino acid sequence of instant SEQ ID

NO: 10, , absent evidence to the contrary. See, for example, MPEP § 2112, which states "[w]here applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection. 'There is nothing inconsistent in concurrent rejections for obviousness under 35 U.S.C. 103 and for anticipation under 35 U.S.C. 102.' In re Best, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA 1977). This same rationale should also apply to product, apparatus, and process claims claimed in terms of function, property or characteristic. Therefore, a 35 U.S.C. 102/103 rejection is appropriate for these types of claims as well as for composition claims.

Therefore, the instant invention is anticipated or obvious over Monia et al. (U.S. Patent 6,300,132).

13. Claims 20 and 22 are rejected under 35 U.S.C. 102(b) or 35 USC 103(a) and claims 17-19, 21 and 23 are rejected under 35 U.S.C. 102(e) or 35 USC 103(a) as being anticipated by or obvious over Stinchcomb et al. (U.S. Patent 5,887,021).

Stinchcomb et al. disclose SEQ ID NO: 2687 (see Table XVIII), as a binding site for a ribozyme of their invention wherein SEQ ID NO: 2687 is 88% identical to instant SEQ ID NO: 2 (an mRNA encoding the polypeptide of instant SEQ ID NO: 10). Therefore, the RNA molecule that is the ribozyme that targets and binds to SEQ ID NO: 2687 of Stinchcomb et al. is an RNA molecule as claimed, because absent evidence to the

contrary, based on sequence complementarity, it will target, bind and inhibit the expression of an mRNA encoding a polypeptide of SEQ ID NO: 10.

Furthermore, since the prior art oligonucleotide meets all the structural limitations of the claims, the prior art oligonucleotide comprises an RNA molecule that is targeted to an mRNA encoding a polypeptide having the amino acid sequence of instant SEQ ID NO: 10, , absent evidence to the contrary. See, for example, MPEP § 2112, which states "[w]here applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection. 'There is nothing inconsistent in concurrent rejections for obviousness under 35 U.S.C. 103 and for anticipation under 35 U.S.C. 102.' In re Best, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA 1977). This same rationale should also apply to product, apparatus, and process claims claimed in terms of function, property or characteristic. Therefore, a 35 U.S.C. 102/103 rejection is appropriate for these types of claims as well as for composition claims.

Therefore, the instant invention is anticipated or obvious over Stinchcomb et al. (U.S. Patent 5,877,021).

Response to Arguments-

Claim Rejections 35 U.S.C. 102(e) or 35 USC 103(a)

14. Applicant's arguments filed 12/15/2005 have been fully considered but they are not persuasive. Applicant has argued that the target sequence disclosed by Pavco et al. is a very non-specific sequence and would never be used by one of ordinary skill in the art to design an antisense target, that there are other different human genes that have 100% or slightly less complementarity with this target sequence and that accordingly this molecule does not target mRNA encoding the polypeptide of SEQ ID NO: 10 (pg. 13). However, as set forth in the prior Action above, the ribozyme (SEQ ID NO: 7749) of Pavco et al. targets nucleotide positions 1382 to 1398 of instant SEQ ID NO: 2 and shares 94.1% complementarity, including 100% identity over the first 5 nucleobases from each of the 5' and 3' ends of each binding arm. Therefore, because nucleotide positions 1382 to 1398 of instant SEQ ID NO: 2 are within an mRNA that encodes a polypeptide having an amino acid sequence of SEQ ID NO: 10, as required by the claims, ribozyme of Pavco et al. anticipates the instant claims drawn to an RNA molecule that targets an mRNA that encodes a polypeptide of SEQ ID NO: 10.

Applicant has also argued that "the mRNA ribozyme of Pavco will not bind to SEQ ID NO: 10 and cleave it" (pg. 13). This argument is not persuasive because the ribozyme of Pavco et al. is not an mRNA and is not applied, in the outstanding rejection, as binding to and/or cleaving SEQ ID NO: 10, but as targeting an mRNA encoding a polypeptide of SEQ ID NO: 10.

Conclusion

15. No claims are allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon B. Ashen whose telephone number is 571-272-2913. The examiner can normally be reached on Monday - Friday, 7:30 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Andrew Wang can be reached on 517-272-0811811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

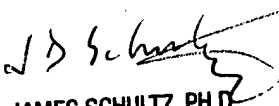
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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Jba


JAMES SCHULTZ, PH.D.
PRIMARY EXAMINER